

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

TRANSLATION

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 24 P 011 PCT		Date of mailing (day/month/year)		See Form PCT/ISA/210 (sheet 2)
		FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/DE2005/000029	International filing date (day/month/year) 12.01.2005	Priority date (day/month/year) 12.01.2004		
International Patent Classification (IPC) or both national classification and IPC A61M25/00				
Applicant MEDI-GLOBE GMBH				

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP Facsimile No.	Authorized officer Telephone No.
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Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language
_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1, 5-9, 12, 13	YES
	Claims	1, 3, 4, 10, 11	NO
Inventive step (IS)	Claims	7-9	YES
	Claims	1-6, 10-13	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims		NO

2. Citations and explanations:

1. Reference is made to the following document:
D1 = DE-A-196 21 420.
2. The present application does not meet the requirements of PCT Article 33(1) because the subject matter of claim 1 as it is currently understood (see Box VIII) is not novel within the meaning of PCT Article 33(2).
 - 2.1 Document D1 discloses, in figure 1 in combination with figure 5, an apparatus for treating human bladder emptying dysfunctions, comprising the following features (the references between parentheses apply to said document):

A catheter (2) that can be inserted into the urethra is provided with a bladder-emptying channel (24) and with a balloon arrangement (4, 5), which serves to seal the bladder and to hold the catheter inside the bladder lumen and which can be filled with a fluid. The balloon arrangement can be filled or emptied with said fluid via at least one channel (6),

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which runs the length of the catheter wall and which is closed at the distal end section of the catheter. An automatically closing valve (16) is disposed in the proximal end section of the catheter. The length of the catheter is dimensioned such that its distal end lies inside the urethra when in the deployed state (see column 4, line 67 - column 5, line 1), and the respective proximal end section carries a hydraulic actuating mechanism (11, 13, 15) for opening the valve. Said actuating mechanism can be charged hydraulically by mechanical pressure acting on the actuating balloon (15) disposed at the distal end section of the catheter, said balloon being filled with actuating fluid and connected to the actuating mechanism via a connecting channel (13). Said actuating mechanism is embodied by the valve (16) having a closure part (32) elastically connected to said proximal end portion of the catheter (2) in such a way that when the actuating balloon (11) is in a non-actuating state, the closure part seals the catheter at said proximal end section. (...), said closure part (32) can be moved out of the sealing system by hydraulic action effected by the actuating balloon (11), via the effective hydraulic pressure built up at said proximal end section, to such an extent that the bladder-emptying channel (24) of the catheter (2) is opened for unobstructed

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passage of urine.

Since all the technical features of claim 1 are anticipated by the device in D1, the claim fails to meet the novelty requirement.

3. Dependent claims 2-6 and 10-13 do not contain any features that, in combination with the features of any claim to which they refer, meet the PCT requirements for novelty or inventive step. The reasons for this are as follows:

- 3.1 Dependent claims 2, 12, 13 concern only minor structural modifications of the device according to claim 1, of the kind that a person skilled in the art routinely makes on the basis of familiar considerations, especially since the resulting advantages are readily foreseeable. Therefore, the subject matter of these claims does not involve an inventive step (PCT Article 33(3)).
- 3.2 The additional features of claims 3 and 4 are likewise anticipated by the device according to D1. Specifically, feature 32 is viewed as a holding element because it is suitable for holding the closure part (3) in its closed position (without said holding element, closure part 3 would release the valve opening very easily, as a result of somewhat greater movement of the proximal end alone, for example). The connection between the end section/closure part 3 and the catheter section distal thereto is viewed as a hinge

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element. Hence, the subject matter of neither of these claims can be considered novel.

3.3 Dependent claims 5 and 6 concern only minor structural modifications of the device according to claims 3 and 4, of the kind that a person skilled in the art routinely makes on the basis of familiar considerations, especially since the resulting advantages are readily foreseeable. Therefore, the subject matter of these claims does not involve an inventive step (PCT Article 33(3)).

3.4 It is noted that there is an obvious difference between the subject matter of figures 3-6 in the present application and the apparatus in D1, but this difference is not clearly defined in the claims. As a result, said claims cannot be considered novel and/or inventive.

3.5 The additional features of claims 10 and 11 are likewise known from the apparatus in D1, so these claims likewise fail to satisfy the conditions for novelty.

4. The additional features defined in claims 7-9 (see Box VIII) are not known from the apparatus of D1, so the combination of these features meets the novelty requirement. The technical effect of these features is to enable the actuating fluid to flow into the actuating balloon at a relatively high speed and to flow back out again at a relatively lower speed, thus achieving a controlled and

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limited period during which the closure part is opened. The combination of these features is not rendered obvious by the available prior art.

5. The subject matter of claims 1-13 can be industrially produced and commercialised, so the criterion of PCT Article 33(4) is met.

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

1. The features in the preamble of claim 1 are not followed by reference signs placed between parentheses (PCT Rule 6.2(b)).

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. The application does not conform to the requirements of PCT Article 6, because the subject matter of claim 1 is not clear. The wording "without the use of mechanical means" is not suitable for limiting the extent of the claim or for distinguishing it from the prior art, because it defines negative features. Furthermore, it is questionable, particularly in view of the embodiments disclosed in the application, whether the claimed subject matter can do "without the use of mechanical means", since the inflated proximal end exerts pressure onto a surface of the closure part, which can also be considered a mechanical means. Given that the feature has not been clearly defined, for the reasons stated, it is not taken into consideration in assessing the novelty and/or inventiveness of claim 1.
2. The subject matter of claims 3 and 6 is not clear, because the term "holding element" is vague. Any feature that is suitable for holding any other feature in position relative to another can be considered a holding element. When evaluating the novelty/inventiveness of claims 3-6, this phrase is interpreted very widely. It is likewise unclear what exactly is to be understood by a "separate attachment".
3. The subject matter of claim 7 is unclear within the meaning of PCT Article 6, because it lacks

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significant features. Merely defining the valve does not solve any technical problem and appears to be arbitrary. The technical problem to be solved is defined in claim 8 as a functional feature or a result to be achieved, and the technical features necessary for this are defined in claim 9. For this reason, the combination of all the features defined in claims 7-9 is taken as the basis for assessment.